federal register

FRIDAY, SEPTEMBER 30, 1977

PART VII

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 77N-0166]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

POISONOUS OR DELETERIOUS SUBSTANCES

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This rule establishes procedures for regulating food contaminants and naturally occurring poisonous or deleterious substances in food. This action is being taken to implement those provisions of the Federal Food, Drug, and Cosmetic Act that permit the Commissioner of Food and Drugs to set tolerances and action levels to control the levels of unavoidable contaminants in food. These procedures, which also permit the identification and listing of naturally occurring poisonous or deleterious substances in food, apply to all poisonous or deleterious substances in food, including food contact surfaces, pet food, and animal feed.

EFFECTIVE DATE: October 31, 1977.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: These regulations were proposed in the FEDERAL REGISTER of December 6, 1974 (39 FR 42746). Several comments were received in support of the proposed regulations; others supported the general approach but opposed specific provisions. The Commissioner's responses to most of the comments received are set forth below.

However, comments that concerned proposed § 122.7(c) of the regulations, which would codify the agency's prohibition against "blending" a food containing a poisonous or deleterious substance above the permitted tolerance with less contaminated food, have not yet been fully evaluated. The issue of "blending" remains under study within FDA, and the prohibition will not be codified at this time. Until the issue is resolved, the agency's long-standing prohibition against "blending" remains in effect.

When these regulations were proposed, regulations codified in 21 CFR Parts 121 and 122 (now Parts 109 and 170-189, recodification was published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) applied to food for human use as well as pet food and animal feed. Subsequently, regulations covering pet food and animal feed were recodified separately from the regulations covering human food. The pet food and animal feed regulations are now codified in 21 CFR Parts 509 and 570 (recodification from Parts 121 and 122 was published in the FEDERAL REGISTER of September 10, 1976 (41 FR 38618)). This document, therefore, establishes identical regulations in Parts 109 (food for human consumption) and 509 (pet food and animal feed). The changes in 21 CFR Part 181 were incorporated into Subchapter E for pet food and animal feed under 21 CFR 570.13.

1. Comments stated that FDA should never permit the sale of contaminated food.

The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities. This is not a modern phenomenon. Wholesome foods have inevitably been the carriers of levels of contamination beyond the capability of contemporary processing methods to eliminate and sometimes even detect. At best, therefore, specifications for "food grade" substances can be established, as has been done in the Food Chemicals Codex, to ensure that only minimal levels of contaminating substances are present. Where more significant levels of contamination occur unavoidably, action levels or tolerances may be established under Part 109 (formerly Part 122), of the regulations to ensure the safety of the food.

2. One comment suggested that the label of a contaminated food bear the warning "hazardous to health."

The Commissioner advises that tolerances and action levels will be established at levels intended to ensure that food marketed is not hazardous to health. The suggested warning would therefore be unnecessary and inappropriate. If any food is found to be hazardous to health, FDA will not permit it to be distributed in interstate commerce.

3. A number of comments argued that the distinction in the act between "added" and naturally occurring poisonous or deleterious substances is a distinction between substances introduced into the food chain through the agency of man and those introduced through the force of nature.

The Commissioner concludes that there is no basis for basing a distinction between "added" and naturally occurring contaminants on the presence or absence of human intervention. If that distinction were to be adopted as the proper interpretation of the statute, it would be necessary to ascertain the precise means by which a contaminant was introduced into the environment, often in historic time, before taking regulatory action. It makes little sense to argue that a contaminant that was introduced into the environment by man generations ago should be regarded differently from contamination caused, for example, by geological phenomena, such as contamination of water by mercury. There would be regulatory problems in trying to ascertain the role human activity played in introducing a contaminant. For example, in the case of contamination occurring through mercury leaching into water from geological sources, it would presumably be necessary to determine whether man's activities exposed more geological surfaces to the waters than would naturally have been exposed. Such an expensive and protracted inquiry would provide no additional information upon which to determine the level of contamination that can be safely tolerated. Moreover, there is nothing in the statute that suggests that the definition of an "added" poisonous or deleterious substance is related to human involvement.

4. One comment contended that the language "any poisonous or deleterious substance added to any food" in section 406 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346) contemplates addition through the agency of man since the term "added" is "used as an active verb."

The Commissioner notes that the comment discussed only the initial portion of section 406 of the act. The section goes on to identify two circumstances in which "added" poisonous or deleterious substances may be permitted: (1) Where the substance is "required in the production" of a food, and (2) or where the substance "cannot be avoided by good manufacturing practice." Although the language of the first circumstance connotes human action, the language of the second does not.

5. One comment stated that the legislative history of the act demonstrated that the term "added" poisonous or deleterious substances referred to substances that became a component of food through the agency of man. In support of this contention, the comment quoted from the testimony of Walter Campbell, then Chief of the Food and Drug Administration, who was concerned with contamination resulting from the "development of the country and the extension of industrial activities." The comment also emphasized Mr. Campbell's examples of smoke contaminating sugar with arsenic and pesticides spray residues in support of its argument that the concept of "added" poisonous or deleterious substances was limited to food contaminants introduced into the environment by man. The comment also cited a 1934 Senate committee report that stated that the amended statute covered all contaminants "whether that constituent is added by man or put there by nature." In addition, the comment emphasized language in the report that stated "it is immaterial to the welfare of the consumer whether a poison in his food is introduced by artifice or occurs naturally." The comment argued that this testimony and committee report support the conclusion that the term "added" poisonous or deleterious substance pertains only to those substances for which human activity is responsible.

The Commissioner concludes that the legislative history cited in the comment does not support the contention that "added" poisonous or deleterious substances are only those that become a

component of food through the agency of man. Industrial development was seen as leading to the appearance of additional contaminants, but there is nothing in the legislative history to suggest that the often remote human connection with food contaminants was to be the basis for permitting tolerances to be established. It is implausible that Congress would have intended that, before establishing a tolerance, an inquiry into the source of a contaminant be made to determine whether human activity, perhaps generations earlier, may have set in motion events leading to the contamination.

The cited language in the committee report focused on the fact that naturally occurring poisons were being covered by the statute for the first time. Consequently, the casual reference to substances "added by man" is of limited significance, as it refers to an unchanged provision of the statute. Moreover, the reference to "added" substances as being those "introduced by artifice" connotes a concept different from contamination as a result of human activity.

6. One comment asserted that the few judicial decisions that have interpreted the statutory words "added" and "not * * * added" in the act do not support the definition established in the regulation. The comment claimed that "United States v. 1200 Cans, Pasteurized Whole Eggs," 393 F. Supp. 131 (N.D. Ga. 1972), was of limited precedential value because of parties stipulated that *Salmonella* in frozen eggs is an added poisonous or deleterious substance. Morever, the comment argued, *Salmonella* is not, like trace elements of natural origin in living organisms, a natural constituent of the host food, possessing potentially nutritional or other valuable properties at low levels and toxic properties at higher levels. The comment asserted that the case "United States v. 1,600,800 Pounds of White Corn," Civil No. T-4173 (D. Kan., Dec. 18, 1970), was distinguishable because the court found that there is no minimum or base line level of aflatoxin commonly found in foods. The comment argued that the Commissioner has ignored "United States v. 1232 Cases of American Beauty Brand Oysters," 43 F. Supp. 744 (W.D. Mo. 1942), which squarely held that shell fragments in cans of oysters are not "added" substances under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)).

The Commissioner advises that since publication of the proposed regulation, another court has interpreted the meaning of the term "added," a decision that supports the Commissioner's position. In the "United States v. An Article of Food Consisting of Cartons of Swordfish," 395 F. Supp. 1184 (S.D. N.Y., 1975), the court stated:

> The government also contends that mercury in swordfish is an added substance within the meaning of 21 U.S.C. § 342(a)(1) * * *. According to the government, the test for determining whether a substance is added is whether it occurs naturally in the food * * *. We agree with the government's position on the point. We find unpersuasive claimant's argument that mercury could not be an added substance because it has been found in fish for centuries. Assuming this to be so, it adds nothing to the question of whether mercury is naturally produced by fish and thus whether it is an added substance within the meaning of the statute.

That *Salmonella* is entirely foreign to frozen eggs and aflatoxin entirely foreign to white corn do not diminish the precedential value of the decisions cited with respect to contaminants identical to naturally occurring components of an organism. It is wholly consistent with the principle of the decisions that any amount of a substance above that naturally occurring is "added" within the meaning of the act. This is the interpretation codified in proposed § 122.3(d), now § 109.3(d).

The Commissioner also believes that the case "United States v. 1232 Cases of American Beauty Brand Oysters" supports the regulations. The court in that case held that shell fragments were not "added" within the meaning of the act because they were, like fish bones, inherent in the food. The case supports the thrust of § 109.3(d) which is that the test of whether a substance is "added" is whether it is intrinsically part of the food.

7. One comment stated that living organisms contain a variety of naturally occurring trace elements whose precise biological role is unknown but whose presence at low levels may be essential. The comment contended that the definitions in the proposed regulation would expand the class of "added" poisonous or deleterious substances to encompass trace elements, such as heavy metals, absorbed by animal organisms from their natural environment.

The Commissioner advises that the distinction drawn in the act, and in the regulations, between "added" and naturally occurring poisonous or deleterious substances is between substances that are inherent and those that are not. If a trace element, such as a heavy metal, is essential to the biological function of an animal, then it is inherent to that animal and it is not to be regulated as an "added" substance, unless it has been increased above the natural level by environmental contamination. If a substance is absorbed from a contaminated environment, in greater than normal amounts, it is not appropriate to regard it as naturally occurring, but to regard it as a contaminant and to take any appropriate action necessary to protect the public health. Contrary to the comment, which argues that this distinction is illogical, the Commissioner finds irrational the belief that the act of biological absorption somehow renders a contaminant "natural". Nothing in the act, or in sound science, suggests that a contaminating substance should be treated specially because it is absorbed by a living organism, or because an organism naturally contains a trace amount of the same substance. The Commissioner's position was implicitly approved in the instance of fish absorbing DDT from the water by the court in "United States v. Ewig Bros. Co.", 502 F.2d 715 (7th Cir. 1974).

8. Comments stated that numerous scientific studies have demonstrated that the level of mercury in ocean fish has remained historically constant and that mercury in marine fish is not primarily a result of manmade pollution but is of natural origin. The comment cited studies indicating that the mercury content of 90-year-old fish, museum specimens of fish caught between 25 and 93 years ago, and various prehistoric fish are of the same order of magnitude as the mercury content of living fish of the same species. The comments argued that since the level of mercury content of the fish has not changed over time, it should not be regarded as an "added" substance but rather as naturally occurring.

The Commissioner believes that the act does not contemplate treating a contaminant differently because it has persisted in the environment for a long time. If the comment's interpretation were correct, the validity of a tolerance for a persistent contaminant would eventually be placed in doubt on the ground that the passage of time has transformed the substance from "added" to naturally occurring even though the levels occurring pose the same risks to human health. Nothing in the act supports such a result. Moreover, the comment's position was specifically considered and rejected by the court in "United States v. An Article of Food Consisting of Cartons of Swordfish", discussed above.

9. One comment questioned whether, if a very substantial portion of a commodity contains, despite all efforts, some level of a mycotoxin, that mycotoxin is an "added" substance. The comment noted that "added" was defined in the regulations as encompassing all ingredients that are not inherent parts of a food, and stated that, under the conditions identified, it would seem that mycotoxins are not necessarily "added" substances. The comment stated that certain manmade substances such as pesticides have become a component of the environment and, like certain natural substances such as mycotoxins widely occurring in nature, would not seem always to be "added" substances within the meaning of the act.

This comment points up the problem of looking only to the current state of the environment to determine whether a substance in food is "added." Certain pesticides have become ubiquitous environmental contaminants and are found in nearly all food. Nevertheless, it is clear that such pesticides are not intrinsic parts of food and should not be regarded as such. The act does not contemplate that serious contamination should be subject to lesser controls than minor contamination, which would be the result if ubiquitous contaminants were "natural" while other, less universal contaminants were regarded as "added." The Commissioner therefore concludes that under the act the test for determining whether a substance is "added" or natural is whether it is necessarily an inherent part of the food, in which case

it is natural. Otherwise it is "added" under the law. Thus, in the example of mycotoxins suggested by comment, the inquiry is not whether all lots of the commodity contain mycotoxin contamination, but whether the mycotoxin is inherently part of the food. This approach will permit adequate control over contaminants, from whatever source, and is the approach contemplated by section 406 of the act.

10. One comment requested clarification of FDA's policy concerning "environmental contamination." The comment gave as an example that corn grown in South Dakota averaged 0.40 part per million (ppm) selenium, while corn grown in Indiana averages 0.04 ppm selenium. The comment stated that these differences are presumably due to differences in selenium content of the soil. The comment questioned whether the differences between 0.04 and 0.40 ppm is "added" selenium. The comment interpreted the regulations, in referring to environmental contamination, as treating increased levels of substances to be "added" only when the increase is caused by man.

The Commissioner does not agree with the comment's interpretation. A substance is "added" within the meaning of the statute when it is increased to abnormal levels through intervening circumstances; these need not involve human intervention, but could involve merely the kinds of geological processes that raise the concentration of a toxic trace element to unusually high concentration in a particular locality. If food may pose a risk to health because of the abnormally high mineral content of the soil in which it is grown, it is appropriate under the act that the Commissioner take action to protect the public health. To repeat, contamination of concern is in no way limited to that which can be attributed to man.

11. One comment stated that the reason we have poisons in our food is due mainly to governmental agencies that allow pesticides to enter the food chain. The comment stated that if farmers knew that the contaminated foods could not be marketed, they would use more natural methods to prevent crop destruction.

The Commissioner advises that the use of pesticides is regulated by the U.S. Environmental Protection Agency (EPA), which establishes conditions for their safe use and tolerance levels for residues resulting from such use. Nothing in these regulations would permit the sale of food that was contaminated beyond the established tolerance or action level or was contaminated through unlawful use of a pesticide or any other added substance except in the rare instance in which such contamination is of such magnitude that destruction of the food would constitute a substantial adverse impact on the national food supply and then only if the food itself is safe for consumption.

12. One comment requested clarification of the meaning of a "poisonous or deleterious substance." The comment stated that a substance may be beneficial or even essential at one level, and yet poisonous or deleterious at a higher level.

The language "poisonous or deleterious substance" appears in section 402(a)(2) of the act (21 U.S.C. 342(a)(2)), and it is not further defined. The Commissioner concludes that clarification of the term is not necessary for purposes of these regulations. The issue in an administrative proceeding to establish a tolerance or action level is the level necessary to protect the public health. Accordingly, it is unnecessary to specify in the abstract what constitutes a "poisonous or deleterious substance."

13. One comment stated that proposed § 122.6(b)(2) (now § 109.6(b)(2)), which provides that a tolerance will be established at a level "sufficient for the protection of the public health," fails to define what constitutes "sufficient" in terms of a margin of safety. The comment stated that if FDA plans to allow such margins, the regulations should so specify with particularity.

The Commissioner advises that it is not possible to specify in advance the margin of safety that will be used for any given contaminant. Particularly in the case of action levels, available data on safety may be so limited that it will be unclear what margin of safety is being provided. Nevertheless, it may be appropriate to establish an action level based on the little data that are available. Also, as was the case, for example, in the proposed action level for mercury in fish and shellfish (December 6, 1974, 39 FR 42738), the margin of safety may vary greatly depending upon how much of the food a particular individual consumes. So far as possible, a proposal to establish a tolerance and the supporting material on file with the Hearing Clerk in the case of an action level will provide information from which it may be concluded what margin of safety is being established. Comments could then address the question whether the margin is sufficient under the circumstances.

14. One comment questioned the language of proposed § 122.4(b) (now § 109.4(b)(1)) which states that an action level "may prohibit any detectable amount of the substance in food." The comment was concerned that nothing more was said about methodology in the regulations. The comment questioned whether the existence of an action level would be dependent upon a specifically approved method of detection.

The Commissioner advises that in establishing an action level or tolerance he will specify the method of detection that is to be used to ensure compliance with the tolerance or action level.

15. One comment referred to the language in proposed § 122.4(a) (now § 109.4(a)) that a tolerance may be established at the level of zero. The comment stated that "zero" depends upon the sensitivity of the method, and suggested that it would be more accurate to state that a tolerance may be established at "no detectable amount of the substance in the food."

The Commissioner agrees with the comment and has revised the regulation accordingly. The Commissioner advises that when a tolerance is established at the level of zero, a method of analysis will always be specified in the regulation establishing the tolerance.

16. One comment opposed proposed § 122.7(a) (now § 109.7(a)), which states that tolerances and action levels will be established at levels "based on the unavoidability of the poisonous or deleterious substance concerned." The comment asserted that section 406 of the act does not permit establishing a tolerance based on a substance's degree of unavoidability, but must be confined to toxicological aspects. The comment asserted that a potentially offending substance need not be eliminated from a class of foods where it is present at completely safe levels simply because it can be eliminated. The comment asserted that FDA has a duty to permit theoretically avoidable but nevertheless safe levels of poisonous or deleterious substances.

The Commissioner advises that the standard of unavoidability established by section 406 of the act is whether the substance can be avoided by good manufacturing practice. If a substance can be avoided by good manufacturing practice, it is deemed by section 402(a)(2)(A) of the act to be unlawful at any level. If a substance cannot be avoided, the Commissioner is expressly directed by section 406 of the act to "take into account the extent to which the use of such substance * * * cannot be avoided" in the production of food. Therefore, the agency must consider the degree of unavoidability of a substance and not simply toxicological aspects.

17. Comments contended that the section on unavoidability (§ 122.7, now § 109.7) does not adequately define the term. The comments stated that adulteration is not unavoidable simply because all purveyors of a food product produce a similarly adulterated item. They stated that customary practice of the industry is not the measure of duty or due care, and that FDA should make clear in this section that objective capability, and not industry practice, defines unavoidability.

As noted above, the act defines an unavoidable substance as one that cannot be avoided by good manufacturing practice. The Commissioner agrees that an industry's customary practice does not necessarily constitute good manufacturing practice. Section 122.7 (now § 109.7) states that the manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible. However, the specific criteria for determining good manufacturing practice will vary. An attempt to define particular circumstances in which an industry's practice does not constitute good manufacturing practice would be beyond the scope of these regulations.

18. Comments objected to the definition of "food" in proposed § 122.3(e) (now § 109.3(e)) because it is different from the definition of "food" in section

201(f) of the act. One comment asserted that indirect food additives, that is, substances migrating to food from food-contact articles, are not foods within the meaning of the definition of section 201(f).

The Commissioner advises that all food additives are "foods" under the law. Moreover, all substances migrating from food-contact surfaces are "foods" within the meaning of the act. This position has been upheld by the courts in *United States* v. *Articles of Food*, 370 F. Supp. 371 (E.D. Mich. 1974), and in *Natick Paperboard Corp.* v. *Weinberger*, 389 F. Supp. 794 (D. Mass. 1975), aff'd, 525 F.2d 1103 (1st Cir. 1975). Thus, the regulation simply clarifies the scope of the act for the benefit of the public and regulated industry. Under Part 109 a tolerance or action level may be established for an unavoidable contaminant of a packaging material or other food-contact article. For example, the existing (stayed) tolerance for polychlorinated biphenyls establishes a tolerance for their presence in paper packaging materials (21 CFR 109.30(a)(9), formerly 21 CFR 122.10(a)(9)).

19. One comment suggested that there should be different definitions for "food" and "feed" because in many instances the poisonous or deleterious substance in question should be treated differently depending on whether it is intended for human or animal consumption.

The Commissioner agrees that different tolerances or action levels may be established for human and animal food. These differences will be reflected in the individual tolerances or action levels established, where appropriate. Changing the definition of "food" would not facilitate this approach, however, nor is it necessary to its implementation.

20. One comment stated that it is unrealistic to establish tolerances or action levels for contaminants that are equally applicable to human food and animal feeds. The comment stated that animal feeds and human food should be considered separately throughout the regulations.

As noted, the Commissioner agrees that it will often be appropriate to establish different tolerances or action levels for human food and animal feeds.

21. The proposed regulations provided for the establishment of action levels through informal (i.e., notice and comment) rule making. The Commissioner has reconsidered this aspect of the proposal, and for the reasons discussed below, concludes that an alternative procedure is preferable. The approach adopted will conserve limited FDA resources while preserving the opportunity for the public to comment upon any action level set and the scientific bases for the decision.

In the preamble to the proposal, the Commissioner stated that action levels, as opposed to tolerances under section 406 of the act, are appropriate in dynamic circumstances. Thus, an action level is appropriate if industrial practices are improving so quickly that the extent to which a substance is avoidable changes significantly from year to year, or if toxicological data are scanty or conflicting but additional data are being developed. The procedures required by section 406 of the act, including a public hearing and the requirement of substantial evidence to support a tolerance, contemplate ample evidence, and a relatively stable situation, in which any tolerance promulgated will be appropriate for a relatively long period of time.

There is an inherent conflict between the dynamic circumstances in which an action level is appropriate and the use of rule making to set such a level. Although the time required to set an action level through informal rule making is less than that required for a tolerance under section 406 of the act, establishment of action levels through informal rule making would still involve a substantial amount of time and agency resources. Because of the time required to promulgate an action level and the dynamic circumstances in which action levels are used, the possibility exists that an action level will be outdated soon after it is promulgated, in which case the process would have to begin anew. The potential for wasteful expenditure of agency resources has persuaded the Commissioner that a simplified procedure for adopting action levels should be used.

In so concluding, however, the Commissioner is mindful of the need to provide for public access to, and review of, the data on which FDA relies in setting an action level and for an opportunity to comment upon the level set. The bases and rationale for action levels cannot be shielded from the public if the agency's decisions are to be credible. In evaluating various alternative procedures for setting action levels, the Commissioner has given great weight to the extent to which specific alternatives would satisfy this need.

The Commissioner recognizes that the approach described below and adopted in § 109.4(b)(2) of the regulations may prove not wholly satisfactory. The Commissioner is committed to reviewing the procedure periodically and to proposing revisions if they appear to be appropriate.

Under § 109.4(b) of the regulations, when the agency sets an action level for a specific poisonous and deleterious substance, a notice will be published in the FEDERAL REGISTER announcing that fact. Before the notice is published, the FDA will place on file with the Hearing Clerk all pertinent data and information regarding the substance, including FDA memoranda analyzing those data and discussing the rationale for the level that has been chosen. The notice will explicitly call attention to the material placed on file with the Hearing Clerk. Additionally, the notice will invite and specify a time for public comments on the level. FDA will review any comments received and, as part of the continuing process of reviewing action levels, modify any level if the comments warrant that action. Any interested person may petition the FDA to set a different action level under the procedures set forth in 21 CFR Part 10 (Subpart A of Part 2, prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)).

On occasion it may be necessary to set an action level to respond to any "emergency" situation. In such a case, a memorandum will be placed on file with the Hearing Clerk stating that an action level has been set. As soon as possible thereafter, a notice will be published in the FEDERAL REGISTER to the same effect.

Because of the dynamic circumstances in which action levels are used, it will frequently be necessary to revise a particular action level before a notice can be published in the FEDERAL REGISTER. A notice will be published as soon as possible whenever an action level is changed. The Commissioner anticipates that a notice will be published in the near future setting forth all existing action levels for poisonous and deleterious substances.

22. One comment questioned whether there is any authority or justification for section 406 tolerances for food additives that may be regulated under section 409 of the act. The comment asserted that food additives are entirely avoidable, as distinquished from the unavoidable contaminants with which section 406 of the act deals.

The Commissioner agrees in part with the comment. Tolerances under section 406 of the act (and action levels) should not be established in Part 109 for intentionally added food ingredients or for components of food-contact articles that serve a functional purpose in the food-contact article. Tolerances under section 406 of the act and action levels may be established only for contaminants of food or food-contact articles, such as the tolerances established for polychlorinated biphenyls unavoidably present in several classes of food and in paper-packaging materials (21 CFR 122.100, now 21 CFR 109.30). Such contaminants may include substances that are "food additives" within the meaning of the act if the substances are unavoidable in a particular food; this conclusion was fully discussed in the preamble to the proposed regulations.

The Food and Drug Administration may have occasion to establish an action level for an intentionally used food ingredient or for a functional component of a food-contact article. If questions arise about the safety of a substance that has long been used in food on the assumption that the substance was generally recognized as safe, it might be appropriate to issue an interim food additive regulation under § 180.1 (21 CFR 180.1) (formerly 21 CFR 121.4000) to permit the continued safe use of the substance while the questions are being resolved. However, it might also be appropriate to restrict use of the substance while the interim food additive regulation is being made final. In such a case an action level would be announced to establish the level at which FDA would take action against the substance under section 402(a)(2)(C) of the Act. An in-

terim food additive regulation would be proposed as soon thereafter as practicable. The Commissioner has added a new paragraph (f) to § 180.1 to set forth the conditions under which such an action level may be considered. A similar paragraph has been added to § 181.1 (21 CFR 181.1) (formerly 21 CFR 121.2000) to identify the conditions under which an action level may be established for a prior-sanctioned substance. No action level would be established for an approved food additive, however; the procedure for changing the permitted conditions of use of an approved food additive is that prescribed in section 409 of the act.

The first action levels established for functional components of food-contact articles are to control lead and cadmium migration from pottery and enamelware, lead migration from silver-plated hollowware, and lead migration from cans containing evaporated milk and skim milk to their contents. These action levels currently exist and will continue to be used.

23. Comments recommended that the circumstances described in § 122.8 (now § 109.8) under which an unlawfully contaminated food could be permitted to be marketed should not be as stringent as those circumstances in which there would be a "substantial adverse impact on the national food supply." The comments argued that it is inconceivable that destruction of a single contaminated product could ever have such an impact and suggested that an exception be permitted whenever destruction of the food involved "would cause a needless waste of food and thus an unwarranted economic loss to the consuming public." Another comment suggested that the criterion should be whether the destruction or diversion of the food involved would "contribute to an adverse impact on the national food or feed supply."

The Commissioner concludes that it is not appropriate to sanction the essentially routine marketing of unlawfully contaminated food as was suggested by these comments. The act permits establishing tolerances and action levels for food that has been unavoidably contaminated. If, however, the food was at some stage of its production unlawfully (i.e., avoidably) contaminated, then the act contemplates that such food shall ordinarily not be marketed. Consequently, the Commissioner concludes that such food should be permitted to be marketed only in the most extraordinary circumstances.

The proper functioning of the agency's regulatory program requires that unlawfully contaminated food ordinarily be destroyed to make unlawful action unprofitable. The fact that the present owner of the food may not have been responsible for the avoidable contamination is not a convincing reason for departing from this policy. To create an exception for persons who unknowingly purchase contaminated foods would permit persons engaged in illegal conduct to profit from their illegal actions. If unlawfully contaminated food were permitted to be sold, then its owner would have no cause of action for damages in a civil action against the person responsible for the contamination. The only action that could be taken against the person responsible for the contamination would be a criminal prosecution, where the government is required to prove guilt beyond a reasonable doubt, and where the penalties imposed are likely to be small in relationship to the value of the goods. Consequently, the Commissioner concludes that it is necessary for proper enforcement of the act that unlawfully contaminated food ordinarily be seized and destroyed, notwithstanding the fact that it may be at the time of such destruction in the hands of an innocent party, and notwithstanding the fact it may on occasion be safe for consumption.

24. One comment sought clarification of § 109.8 which refers to "a substantial adverse impact on the national food supply" and stated that carload or warehouse lots of adulterated foods should not fall into this category. Another questioned whether the unavailability of one variety of fruit or vegetable would result in a "substantial adverse impact." Other examples posed included whether a few pennies per week inflation in the price of food would constitute such an adverse impact and whether the bankruptcy of a major food company as a result of destruction or diversion of certain food would constitute a substantial adverse impact on the national food supply.

The Commissioner agrees that the loss of carload or warehouse lots of adulterated food would almost never have a substantial adverse impact on the national food supply. It would not be appropriate to examine and pass on all possible circumstances at this time, however. In accordance with § 109.8(a)(2), whenever possible an exemption will be issued only after opportunity for public comment.

25. One comment stated that, if unlawfully contaminated food is permitted to be sold in accordance with § 109.8, FDA should investigate the reason for the contamination and not exclude civil or criminal action against responsible individuals even though the food was sold.

The Commissioner agrees with this comment. Granting an exemption does not exempt from liability the person who unlawfully contaminated the food. The Food and Drug Administration would investigate and initiate appropriate regulatory action against persons responsible for unlawfully contaminated food, even if the food were permitted to be sold.

26. Comments objected to the provision in § 109.6(d) that applies when the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act (21 U.S.C. 371(e)(2)) by the filing of an objection. Under that section, the order establishing the tolerance is deemed to be an order establishing an action level until final action is taken upon the objection. Comments argued that if a hearing is requested, the reasonableness of the tolerance would be in doubt and that, therefore, its enforcement as an action level would not be justified. One comment suggested that a tolerance become an action level only in cases where a hazard to health is involved.

The Commissioner notes that if the substance that is the subject of the tolerance is a food additive, it is unlawful at any detectable level, under section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)). Thus, if a tolerance is stayed by an objection, the presence of the substance is unlawful at any level, and regulatory action may be taken; an action level is appropriate to determine the level at which action should be taken. This approach was approved by the Court of Appeals in "Natick Paperboard Corp. v. Weinberger," cited above.

If the substance is not a food additive, but is an unavoidable "added" poisonous or deleterious substance, then action may be taken pursuant to section 402(a)(1) of the act, which remains applicable to a particular substance until a tolerance is in effect. Thus, for substances that are not food additives, a tolerance indicates the level at which the Commissioner will take action against a substance on the ground that the level may be injurious to health. The establishment of a tolerance does not make unlawful what would otherwise be lawful; it may, however, make lawful what would otherwise be unlawful.

The Commissioner rejects the suggestion that a tolerance stayed by an objection should become an action level only in cases where a hazard to health is involved. By hypothesis, in the case of poisonous or deleterious substances, a potential hazard to health always exists, and that is the basis upon which action levels and tolerances are established.

27. One comment asserted that FDA may not avoid the procedures of section 406 of the act by establishing an action level. The comment stated that where Congress has specified with particularity the hearing procedures by which a certain administrative action may be taken, an agency is without authority to depart from the congressionally mandated process. The comment asserted that FDA is obligated to elect one of two courses: it must either disclaim any intent to attach the force of law to its action levels, or it must adopt those action levels as tolerances under section 406 of the act and in accord with the procedures specified in section 701(e) of the act.

The Commissioner disagrees. As to those substances that would be illegal at any level in the absence of an action level, e.g., because they are food additives, the courts have upheld FDA's authority to issue action levels. Those cases were cited in the preamble to the proposed regulation. As to other substances, the act clearly contemplates that the Government may proceed against a contaminated food under section 402(a)(1) of the act when no tolerance is effective. Furthermore, in light of the procedure adopted for establishing action levels in the regulations, this point, for the present at least, is moot.

28. One comment included data and arguments concerning the tolerance for polychlorinated biphenyls.

The Commissioner notes that the tolerances for polychlorinated biphenyls were not proposed in the FEDERAL REGISTER of December 6, 1974, but were simply reprinted because the section number is being changed.

29. One comment stated that the republication of the tolerance for polychlorinated biphenyls in paper-packaging materials should state that the regulation is stayed.

The Commissioner agrees and has added an appropriate note.

30. One comment offered an interpretation of the proviso in section 402(a)(2)(C) of the act, which provides that a pesticide chemical present in a processed food is lawful if the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. The comment interpreted the term "ready to eat" as permitting a processed food to contain a higher concentration of pesticide than is permitted for the raw agricultural commodity if the food is "disbursed" in other food when consumed in a manner such that the pesticide level of the mixture is below the tolerance. As an example, the comment cited dehydrated peppers, which contain pesticide residues greater than the tolerance for raw peppers because of the dehydration; the comment contended that the dehydration pepper was not "ready to eat" until it had been incorporated into a finished food and that the tolerance is properly applied to the entire finished food into which it was incorporated.

The Commissioner disagrees with the interpretation of the act offered by the comment. The term "ready to eat" does not permit compliance with a tolerance to be determined after the food has been mixed with other food; the term applies when a food is to be modified before use, e.g., by hydration.

One of the prinicipal purposes for which a tolerance is established by regulation is to provide a readily ascertainable standard by which FDA and affected persons can determine whether a particular lot of food conforms to the requirements of the law. Under the interpretation suggested by the comment, there would be no definite standard to determine whether a particular lot of dehydrated peppers complies with the law. Instead, its legality would turn on uncertain subsequent events involving the manner in which the food was to be used. By contrast, foods that are not ready to eat because they must be modified in a particular way may be so modified prior to analysis, and compliance may thus be determined with certainty. In the event that processing increases the concentration of a pesticide, the act permits a tolerance to be established under section 409 of the act; this procedure permits a clear, enforceable limit and is the procedure to be followed.

31. The Commissioner has revised proposed § 109.4(b) to delete the reference to section 402(a)(1) of the act. This reference was inconsistent with § 109.6(c), which establishes the standards for an action level. The Commissioner has also revised proposed § 109.6(d), which refers to the statutory authority for issuing tolerances and action levels, by explicitly stating the pertinent sections of the act.

32. The Commissioner has revised proposed § 109.6(a) to clarify the relationship of FDA and EPA in establishing tolerances and action levels for added poisonous and deleterious substances that are also pesticide chemicals. The regulations that EPA issues under sections 406, 408, and 409 of the act will establish tolerances; FDA will implement action levels under the criteria of these procedural regulations. Upon FDA's request, EPA will recommend an action level based on the criteria set forth in these procedural regulations.

33. The Commissioner advises that the prohibition in the regulations against marketing unlawfully contaminated food is not intended to change the agency's current policy permitting the diversion of contaminated human food into use as animal feed when such diversion would pose no significant risks to human or animal health. Proposed regulations will be published in the FEDERAL REGISTER to formally establish the permissible conditions for such diversion.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 408, 409, 701(a), 52 Stat. 1045–1046 as amended, 1049 as amended, 1055, 68 Stat. 511–518 as amended; 72 Stat. 1785–1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371(a))) and under authority delegated to him (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. By revising Part 109 to read as follows:

PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

Subpart A—General Provisions

Sec.

109.3 Definitions and interpretations.
109.4 Establishment of regulations.
109.5 Petitions.
109.6 Added poisonous or deleterious substances.
109.7 Unavoidability.
109.8 Exemptions.
109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

109.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

Subpart C—Naturally Occurring Poisonous or Deleterious Substances—[Reserved]

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045–1046 as amended, 1049 as amended, 1055–1056 as amended, 68 Stat. 511–518 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371).

Subpart A—General Provisions

§ 109.3 Definitions and interpretations.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes human food and substances migrating to food from food-contact articles.

§ 109.4 Establishment of regulations.

(a) When appropriate under the criteria of § 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b)(1) When appropriate under the criteria of § 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define the level of contamination at which a food will be deemed to be adulterated. An action level may prohibit any detectable amount of the substance in food.

(2) Whenever an action level is established, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Hearing Clerk before the notice is published. The notice shall invite public comment on the action level. Regulatory action may be taken at any time after an action level is established, and need not await publication of the notice. An action level may be changed at any time if the protection of the public health so requires. A notice shall be published in the FEDERAL REGISTER as soon as practicable after an action level is changed.

(c) A regulation may be established in Subpart C of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 109.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the

form set forth in § 10.65 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 109.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under section 406, 408, or 409 by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

§ 109.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 109.8 Exceptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

§ 109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's. The source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packing materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before September 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerance for Unavoidable Poisonous or Deleterious Substances

§ 109.30 Polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

NOTE.—At 38 FR 22794, Aug. 24, 1973, the following appeared concerning § 109.30(a)(9) (formerly 122.10(a)(9)):

* * * § 109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973, containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

2. By adding new paragraph (f) to § 180.1 to read as follows:

§ 180.1 General.

* * * * *

(f) Where appropriate, an emergency action level may be issued for a substance subject to paragraph (a) of this section that is not an approved food additive, pending the issuance of a final interim food additive regulation. Such an action level shall be issued pursuant to sections 306 and 402(a) of the act to identify, based upon available data, a safe level of use for the substance. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed interim food additive regulation. Where the available data do not permit establishing an action level for the safe use of a substance, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

3. By adding new paragraph (c) to § 181.1 to read as follows:

§ 181.1 General.

* * * * *

(c) Where appropriate, an emergency action level may be issued for a prior-sanctioned substance, pending the issuance of a final regulation in accordance with paragraph (b) of this section. Such an action level shall be issued pursuant to section 402(a) of the act to identify, based upon available data, conditions of use of the substance that may be injurious to health. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed regulation in accordance with paragraph (b) of this section. Where the available data demonstrate that the substance may be injurious at any level, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

PART 509—UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

4. Part 509 is revised to read as follows:

Subpart A—General Provisions

Sec.	
509.3	Definitions and interpretations.
509.4	Establishment of regulations.
509.5	Petitions.
509.6	Added poisonous or deleterious substances.

509.7 Unavoidability.
509.8 Exemptions.
509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

Subpart C—Naturally Occurring Poisonous or Deleterious Substances—[Reserved]

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045–1046 as amended, 1049 as amended, 1055–1056 as amended, 68 Stat. 511–518 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371).

Subpart A—General Provisions

§ 509.3 Definitions and interpretations.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes pet food, animal feed, and substances migrating to food from food-contact articles.

§ 509.4 Establishment of regulations.

When appropriate under the criteria of § 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b)(1) When appropriate under the criteria of § 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define the level of contamination at which a food will be deemed to be adulterated. An action level may prohibit any detectable amount of the substance in food.

(2) Whenever an action level is established, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Hearing Clerk before the notice is published. The notice shall invite public comment on the action level. Regulatory action may be taken at any time after an action level is established, and need not await publication of the notice. An action level may be changed at any time if the protection of the public health so requires. A notice shall be published in the FEDERAL REGISTER as soon as practicable after an action level is changed.

(c) A regulation may be established in Subpart C of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 509.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 10.65 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 509.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under section 406, 408, or 409 by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent of which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

§ 509.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The mauufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 509.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption, and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on the determination. The notice shall call at-

tention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

§ 509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper foodpackaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes):

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining

compliance with the tolerances established in this section is available from the Hearing Clerk, Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, MD 20857.

NOTE: At 38 FR 22794, August 24, 1973, the following appeared concerning § 509.30(a)(9) (formerly § 122.10(a)(9)):

"* * * § 509.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 509.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Naturally Occurring Poisonous or Deleterious Substances—[Reserved]

Effective date: These regulations shall become effective October 31, 1977.

Dated: September 23, 1977.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc.77–28576 Filed 9–29–77;8:45 am]